K130262

Section 5 510(k) Summary

MAR 1 2013

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of Safe Medical Device Act 1990 and 21 CFR § 807.92. The 510(k) Summary is provided on the next page and is suitable for publication on the FDA website.

I. General Information

Establishment

Siemens Medical Solutions USA. Inc.
51 Valley Stream Parkway
Mail Code G01
Malvern, PA 19355, USA
Registration Number 2240869

Date Prepared

January 31, 2013

Registration Number

2240869

Manufacturers

Siemens Shenzhen Magnetic Resonance Ltd.
Siemens MRI Center
Gaoxin C. Ave., 2nd
Hi-Tech Industrial Park,
Shenzhen 518057, P.R. China
Registration Number 3004754211

Siemens AG
Henkestrasse 127
D-91052 Erlangen, Germany
Registration Number 3002808157

Contact Person

Ms. Nadia Sookdeo
Regulatory Affairs Technical Specialist
Siemens Healthcare

Siemens Medical Solutions USA, Inc.
Customer Solutions Group
51 Valley Stream Parkway
Mail Code G01
Malvern, PA 19355, USA
Phone: (610) 448-4918
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Device Name

Trade Names:	MAGNETOM ESSENZA
Classification Name:	Magnetic Resonance Diagnostic Device
CFR Code:	21 CFR § 892.1000
Classification:	Class II

Performance Standards

None established under Section 514 the Food, Drug and Cosmetic Act.

II. Safety and Effectiveness Information Supporting Substantial Equivalence

Intended Use

The intended use for the MAGNETOM ESSENZA with *syngo* MR D14 is the same as MAGNETOM ESSENZA that is described in K071925 and cleared on August 14, 2007.

The MAGNETOM ESSENZA with *syngo* MR D14 is indicated for use as magnetic resonance diagnostic devices (MRDD) that produces transverse, sagittal, coronal and oblique cross sectional images, spectroscopic images and/or spectra, and that displays the internal structure and/or function of the head, body, or extremities. Depending on the region of interest, contrast agents may be used. These images and/or spectra when interpreted by a trained physician yield information that may assist in diagnosis.

The MAGNETOM ESSENZA may also be used for imaging during interventional procedures when performed with MR compatible devices such as, in room display and MR-safe biopsy needles.

Device Description

The MAGNETOM ESSENZA is being upgraded with software *syngo* MR D14. The MAGNETOM ESSENZA is a 1.5T, whole body scanner designed for economical optimized reasons. Siemens intends to modify the cover, gradient coil, Physiological Measurement Unit (PMU), Measurement and Reconstruction System (MaRS), update the software and add two new coils for the existing MAGNETOM ESSENZA Magnetic Resonance System.

Substantial Equivalence

Siemens feels that the new system is substantially equivalent to the following predicate devices:

Predicate Device Name-System	*FDA Clearance Number*	*FDA Clearance Date*
Siemens MAGNETOM ESSENZA (1.5T)	K071925	August 14, 2007
Siemens MAGNETOM Avanto (1.5T)/MAGNEOM Aera(1.5T) with *syngo* MR D13A	K121434	November 5, 2012

Predicate Device Name-Coils	*FDA Clearance Number*	*FDA Clearance Date*
Specialty coils for MAGNETOM ESSENZA	K083166	January 13, 2009
14-Channel Extremity Coil For MAGNETOM ESSENZA	K100141	August 27, 2010
2/4-ch Sentinelle Breast Coil	K060873	April 14, 2006

General Safety and Effectiveness Concerns:

The MAGNETOM ESSENZA with software *syngo* MR D14 conforms to the applicable FDA recognized and international IEC, ISO and NEMA standards with regards to performance and safety as recommended by the respective MR FDA Guidance Document.

The device labeling contains instructions for use and any necessary cautions and warnings to provide for safe and effective use of the device.

Risk Management is ensured via a risk analysis in compliance with ISO 14971:2007 to identify and provide mitigation to potential hazards beginning early in the design cycle and continuing throughout the development of the product.

Siemens Medical Solutions USA, Inc. and Siemens AG adhere to recognized and established industry standards, such as the IEC 60601-1 series, to minimize electrical and mechanical hazards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Ms. Nadia Sookdeo
Regulatory Affairs Technical Specialist
Siemens Medical Solutions USA, INc
51 Valley Stream Pkwy
MALVERN PA 19355

March 1, 2013

Re: K130262
Trade/Device Name: MAGNETOM ESSENZA with syngo MRD14 software
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: January 31, 2013
Received: February 1, 2013

Dear Ms. Sookdeo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance..

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Section 4 Indications for Use Statement

510(k) Number (if known) K130262

Device Names: **MAGNETOM ESSENZA**

Indications for Use:

The MAGNETOM ESSENZA with *syngo* MR D14 is indicated for use as magnetic resonance diagnostic devices (MRDD) that produces transverse, sagittal, coronal and oblique cross sectional images, spectroscopic images and/or spectra, and that displays the internal structure and/or function of the head, body, or extremities. Depending on the region of interest, contrast agents may be used. These images and/or spectra when interpreted by a trained physician yield information that may assist in diagnosis.

The MAGNETOM ESSENZA may also be used for imaging during interventional procedures when performed with MR compatible devices such as, in room display and MR-safe biopsy needles.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OVID)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K130262